REMARKS

Claims 1-8, 10-13, 15, 17-21, 23-26 and 28-49 are currently pending in the application and stand rejected. Applicants note that the Office Action refers to a clamping member limitation, which was previously deleted from claim 1 in the amendment in reply to the office action of December 22, 2008.

Objections to the Drawings

The Drawings are objected to as failing to show every claimed feature. Applicants submit amended drawings to overcome the objection. The attached replacement drawing FIG. 5 shows barrier 107 as also clearly shown in FIG. 1, based on earlier drawing amendments. Amended FIG. 4 properly includes reference numbers 217 and 218 in place of 317 and 318.

Support for the amendment to FIG. 4 is found in paragraph [0036], [0058, and [0071] below:

> [0036] In the alternative embodiment of the assembly, the drug container 203 preferably includes a neck 215 as indicated in FIG. 3, wherein the cap 212 includes locking members 216 for grasping the neck 215. Even more advantageously, the drug container also includes an opening sealed by a closure 217, wherein the cap 212 includes a hollow needle 218 for penetrating the closure 217. The alternative embodiment enables the use of conventional drug vials in the assembly according to the invention, something which might be advantageous for practical reasons.
>
> [0058] Even more advantageously, the drug container 203 in the alternative embodiment exhibits an opening sealed by a closure 217, wherein the cap 212 exhibits a hollow needle 218 for penetrating the closure 217.
>
> [0071] In the alternative embodiment, the method advantageously also includes providing the drug container 203 with an opening sealed by a closure 217, providing the cap 212 with a hollow needle 218, and causing the hollow needle 218 to penetrate the closure 217.

Accordingly, Applicants request withdrawal of the objections to the drawings.

Claim Rejections – 35 USC § 112

Claims 1 and 21 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Applicants submit that support is found for the claimed hollow spike and rupturable fluid barrier in at least paragraphs [0036, 0058 and 0071] above and in Fig. 1. The rupturable/ruptured barrier is shown in the figures in the context of the "conventional infusion bags." Support for the barrier being rupturable by an external force is found in at least paragraphs [0031, 0039, 0051, 0063-65] and support for a hollow spike is found in at least paragraphs [0042 and 0079] below.

Regarding support for rupturable by an external force:

[0031] Furthermore, according to the invention, the fluid barrier 107, 109, 108 is designed and arranged to be ruptured by an external force to allow the fluid passage from the drug container to the fluid container, or vice versa. This feature ensures that no premature fluid communication takes place between the drug container and the fluid container.

[0039] In a preferred embodiment of the fluid transfer assembly as indicated in FIGS. 1 and 2, the fluid barrier is made of a brittle polymer member 107, 109, 108 which can be divided along a weakening line by means of the external force. However, within the scope of the invention, it is conceivable with many different designs of the fluid barrier, as long as the barrier provides a safe sealing of the fluid container and/or the drug container, and as long as it is possible for an operator to eliminate the sealing action by means of applying an external force onto the fluid barrier in order to break, rupture, puncture, or dislocate the fluid barrier and open a fluid passage through the barrier.

[0051] In a preferred embodiment of the drug container, the cap 112 includes a protruding member 114 that forms a fluid duct between the drug

container 103 and the second luer-lock connector 113. In doing so, a fluid barrier 109 designed and arranged to be ruptured by means of an external force is provided inside the second fluid duct. Preferably, the fluid barrier is designed and arranged to be ruptured by means of an external force exerted by a person by hand. This is also the case with the other fluid barriers included in the fluid transfer assembly according to the invention.

[0063] The method according to the invention further includes providing the fluid container 101 with a first luer-lock connector 110, 111 on the inlet port 105, 106, providing the drug container 103, 203 with a cap 112, 212 exhibiting a second luerconnector 113, 213, attaching the first luer-lock connector 110, 111 to the second luer-lock connector 113, 213 by means of a luer-lock coupling, applying an external force onto the fluid barrier 107, 109, 108 to open the fluid passage, and creating a positive pressure inside the fluid container 101. According to the invention the method also includes transferring at least part of the positive pressure to the drug container 103, 203 via the fluid passage, and removing the positive pressure from the fluid container 101 in order to initiate transfer of the medical substance 104, 204 from the drug container 103, 203 to the fluid container 101.

[0064] In a preferred embodiment, the method further includes rupturing the fluid barrier 107,108 by means of twisting, bending, or squeezing material portions 119, 120 between the fluid container 101 and the first luer-lock connector 110,111.

[0065] Preferably, the method also includes rupturing another fluid barrier by means of twisting, bending or squeezing material portions 114 between the drug container 103 and the second luer-lock connector 113.

Regarding support for hollow spike:

[0042] In another alternative embodiment as illustrated in FIG. 5, the fluid container 301 includes a protruding, resilient tube 322. The first luer-lock connector 310 of the inlet port 305 is provided on a hollow spike member 323 designed and arranged to be firmly retained inside the tube 322. This embodiment enables conventional infusion bags to be utilized in the fluid transfer assembly according to the invention.

[0079] Furthermore, the method can also include providing the fluid container 301 with a protruding, resilient tube 322, providing a hollow spike member 323 for the first luer-lock connector 310, and inserting the hollow spike member 323 into the resilient tube 322, and/or attaching an infusion line 325 to the inlet port 305, in addition to the first luer-lock connector 310, and providing a third clamping member 329 for compressing the infusion line 325, thereby preventing undesirable fluid passage there through.

Accordingly, Applicants request withdrawal of the rejections under Section 112.

Claim Rejections – 35 USC § 102

Claims 21, 26, 28, 30, 32 and 33 stand rejected under 35 U.S.C. 102(b) as being anticipated by Scarrow (U.S. Pat. No. 5,061,264). This rejection is respectfully traversed.

Claim 21 is directed to a "drug container for use in an infusion system [including] fixed dose of a medical substance, and a cap for sealing said drug container, said cap further comprising a luer-lock connector for attachment to a corresponding connector provided on a **hollow spike that is arranged to be retained inside walls of an inlet port** of a container for infusion fluid, thereby creating a luer-lock coupling, said cap further comprising a protruding member forming a fluid duct between said drug container and said second luer-connector, wherein **fluid barrier able to be ruptured by an external force** is provided inside said second fluid duct.

Shemesh does not disclose that any component of a fluid transfer system may be arranged to be inserted into the inlet port (14) of a fluid container (6). Instead, one end of the inlet port (14) of the

fluid container (6) is connected to a cap (16) that is adapted to be attached to a vial (4) (see figure 1 and see col. 2, lines 43-50), i.e. the inlet port (14) itself is, on the contrary, arranged to be inserted into another component. In particular, the **inlet port** (14) in Shemesh's system is connected to a specially adapted **cap** (16) of a vial (4).

In contrast, the claimed configuration includes a hollow spike member configured to be inserted into a flexible inlet port of a fluid container and a first luer lock connector on the **hollow spike member** is then connected to a corresponding second luer lock connector on a **cap** of a drug container. The **inlet port** in the claimed fluid transfer assembly is not, therefore, **directly** connected to the cap but it is connected to a **hollow spike member** that is in turn connected to the **cap.**

Shemesh does not disclose at least a "drug container [including a] cap further comprising a luer-lock connector for attachment to a corresponding connector provided on a **hollow spike that is arranged to be retained inside walls of an inlet port** of a container for infusion fluid, thereby creating a luer-lock coupling, said cap further comprising a protruding member forming a fluid duct between said drug container and said second luer-connector, wherein **fluid barrier able to be ruptured by an external force** is provided inside said second fluid duct," as recited as independent claim 21. Claims 26, 28, 30, 32 and 33 are likewise allowable at least as depending from claim 21.

Accordingly, Applicants request withdrawal of the rejections under Section 102 and reconsideration of the claims.

Claim Rejections – 35 USC § 103

Claims 1, 3, 8, 10, 12, 16, 19 and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow in view of Shemesh et al. (U.S. Pat. No. 5,817,083).

Claims 13 and 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow in view of Shemesh et al and further in view of Haber et al. (U.S. Patent No. 5,593,028).

Claims 15 and 16 rejected under 35 U.S.C. 103(a) as being unpatentable over Scarrow in view of Shemesh et al and further in view of Vaillancourt (U.S. Patent No. 5,897,526).

Applicants respectfully traverse as set forth below.

Regarding claims 1, 3, 8, 10, 12, 16, 19 and 20, the claimed fluid transfer assembly comprises a hollow spike member provided with a first luer lock connector, which hollow spike member is arranged to be inserted into and retained inside the walls of an inlet port of a fluid container.

As discussed above, Shemesh does not disclose that any component of a fluid transfer system may be arranged to be inserted into the inlet port (14) of a fluid container (6). Scarrow does not cure this deficiency. Instead, Scarrow discloses a fluid container having a rigid inlet port (12) which is provided with a luer lock connector (16). This means that only **specially adapted** components having a corresponding luer lock connector may be **directly** connected to the **inlet port** (12) of Scarrow's system.

In contrast, the claimed hollow spike member of the fluid transfer assembly may be inserted into a flexible inlet port of **any** fluid container (as long as the hollow spike member will thereafter be retained in the flexible inlet port).

Both Scarrow and Shemesh therefore disclose a specially adapted **inlet** port of a fluid container that is directly connected to a corresponding component. Thus, neither Scarrow or Shemesh would lead one of ordinary skill in the art to insert a component into an inlet port such that a corresponding component may then be directly connected to the inserted component. Nor would such a skilled person seek to modify Scarrow's system by replacing the rigid inlet port (12) with a flexible inlet port such as the one disclosed by Shemesh as the Examiner suggests. The rigid inlet port (12) disclosed by Scarrow comprises a luer lock connector (16) at its end. Luer lock connectors are always constituted by **rigid** components to ensure that secure locking is obtained. Thus, even if the skilled person were to replace the rigid inlet port (12) of Scarrow's system with a **flexible** inlet port having a (rigid) luer lock connector at its end, he/she would still not have a fluid transfer assembly according to the present invention. In particular, a hollow spike member could not be inserted into the flexible inlet port having a luer lock connector at its end and only a specially adapted component having a corresponding luer lock connector could be connected to the luer lock connector at the end of the flexible **inlet port.**

In contrast, the claimed fluid transfer system comprises a hollow spike member that may be inserted into **any flexible inlet port** and further components may then be connected to the luer lock connector provided on the hollow spike member, making the claimed fluid transfer system suitable for use with **any fluid container** having a flexible inlet port that will retain a hollow spike member. As

previously discussed, the systems disclosed by Scarrow and Shemesh may only be used with fluid containers having specially adapted inlet ports.

Thus, Neither Shemesh, Scarrow, nor their combination discloses a fluid transfer assembly comprising at least "a hollow spike member arranged to be retained inside walls of said inlet port and provided with a first luer-lock connector, [and] wherein said at least one fluid barrier is designed and arranged to be ruptured by an external force to allow said fluid passage," as recited in independent claim 1. The dependent claims are allowable for at least the reasons discussed with regard to claims 1 or 21. Accordingly, Applicants request withdrawal of the rejections under Section 103 and reconsideration of the claims.

CONCLUSION

It is believed that all of the pending claims have been addressed. However, the absence of a reply to a specific rejection, issue or comment does not signify agreement with or concession of that rejection, issue or comment. In addition, because the arguments made above may not be exhaustive, there may be reason for patentability of any or all pending claims (or other claims) that have not been expressed. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to amendment. Applicants respectfully request consideration of all filed IDS' not previously considered, by initialing and returning each Form 1449.

Applicant requests a one-month extension of time. All fees are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Please apply all charges or credits to Deposit Account No. 06-1050

Respectfully submitted,

Date: 10/23/09

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